114TH CONGRESS
1ST SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of patient records and certain decision support software.

IN THE SENATE OF THE UNITED STATES

_____

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of patient records and certain decision support software.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medical Electronic Data Technology Enhancement for Consumers' Health Act'' or the ''MEDTECH Act''.

SEC. 2. REGULATION OF MEDICAL SOFTWARE.

Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following:

"(o) REGULATION OF MEDICAL AND CERTAIN DECISION SUPPORT SOFTWARE.—

"(1) EXCLUSIONS FROM THE CATEGORY OF DEVICES.—The term 'device', as defined in section 201(h), shall not include the following:

"(A) Software that is intended for administrative and operational support of a health care facility or the processing and maintenance of financial records , appointment schedules, business analytics, communication, information about patient populations, and laboratory workflow processes.

"(B) Software that is intended for the purpose of maintaining or encouraging a healthy lifestyle and are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or disorder.

"(C) Except for software intended to interpret or analyze medical image data for the purpose of diagnosis, cure, mitigation, prevention, or treatment of a disease or condition, electronic patient records, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper

medical chart, which may include patient history records if—

"(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals; and

"(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act as being in compliance with applicable certification criteria adopted under subtitle A of title XXX of such Act.

"(D) Except for software intended to interpret or analyze clinical laboratory test data, software that is intended to transfer, store, convert formats, or display—

"(i) clinical laboratory test report data, results, or findings prior to analysis or interpretation by a health care professional; or

"(ii) clinical laboratory test report data, results, or findings, or related patient

education information with respect to such data, to a patient.

''(E) Except for a device accessory and software that is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, software that—

''(i) is intended to display, analyze, or print medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

''(ii) is intended to support or provide recommendations to a health care professional about prevention, diagnosis, or treatment; and

''(iii) enables the health care professional to independently review the basis for each recommendation that the software presents such that it is not the intent that the health care professional rely solely on any specific recommendations or results provided by such software to make a clinical diagnosis or treatment decision.

''(2) MULTIPLE FUNCTIONALITY PRODUCTS.—In the case of a product with multiple functionality that contains a software function that is excluded under paragraph (1) from the definition of a device under section 201(h) and a function that meets the definition of device under section 201(h), the Secretary shall not regulate the excluded software function of the product as a device, but the Secretary may assess such software function for the purpose of determining the safety and effectiveness of the device function of the product.

''(3) RULES OF CONSTRUCTION.—Nothing in this subsection shall be construed as limiting the authority of the Secretary to—

''(A) exercise enforcement discretion as to any device subject to regulation under this Act; or

''(B) regulate software devices used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans.''.

SEC. 3. QUALITY AND STANDARDS.

The Secretary of Health and Human Services shall ensure that software described in subparagraphs (C), (D), and (E) of subsection (o)(1) of section 520 of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 360j) (as amended by section 3) is consistent with appropriate quality principles and standards for software development and validation.

SEC. 4. CLASSIFICATION OF ACCESSORIES.

Subsection 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended by adding at the end the following:

''(9) The Secretary shall classify an accessory under this section based on the intended use of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used.''.

SEC. 5. CONFORMING AMENDMENT.

Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended by adding at the end ''The term 'device' does not include medical and decision support software described in section 520(o).''.